GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA

UNSTARRED QUESTION NO:3010
ANSWERED ON:21.03.2017
Generic Drug Manufacturers
Kumar Shri P.

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) the details of manufacturers of generic drugs and companies registered for manufacturing of such drugs in the country;
(b) whether these manufacturers are associated with the Food and Drug Administration (FDA) and if so, the details thereof; and
(c) the names of drugs manufactured by the aforesaid companies?

Answer

MINISTER OF STATE IN THE MINISTRY OF ROAD TRANSPORT AND HIGHWAYS; MINISTRY OF SHIPPING AND MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI MANSUKH L. MANDAVIYA)

(a) to (c): Manufacturing of drugs in the country is regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 made thereunder through a system of inspection and licensing. Licenses for manufacturing of drugs are granted by State Licensing Authorities appointed by respective State Governments. However, data regarding manufacturers of drugs and names of drugs manufactured by them is not maintained at Central level. Under the said Act and Rules, there is neither any separate definition for generic drugs nor any separate system of Licensing of generic drugs.

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